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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/811,218	03/16/2001	Brian Thomas O'Neill	PCI0723A	9119
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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
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1624

8

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,218

Applicant(s)

O'NEILL ET AL.

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 64-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of group I, claims 1-63, wherein R³ is not a heterocyclic group and p is 1, in Paper No. 7 is acknowledged. Claims 1-63 will be examined to the extent they embrace the elected group. Claims 64-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter.

The traversal is on the ground(s) that the instant inventions are not distinct and independent and classification has no relevance. This is not found persuasive because of the following reasons.

First of all, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

Both these criteria are to be met with.

Applicants' argument that the instant invention is not distinct and independent is incorrect. The instant core ring can embrace pyrrolidine (p=0), piperidone (p=1) and homopiperidine (p=2). These are distinct cores and there are no equivalency teaching in the prior art such that searching one core will lead total search of all cores embraced. The method of making are distinct and method of uses embraced by one core is not always the same as other cores.

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Applicants have not shown or provided any evidence that pyrrolidine core is same as piperidine core and homopiperidine (azepine) core.

Art, which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. Each can support a patent, as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

Searching all these cores would be a serious search burden as noted before.

It is mandatory, in addition to Chemical Database search (CAS ONLINE), for the examiner to classify and search all these cores and other controlling cores positively recited and made. As matter of fact, search with p= 0 to 2 results in incomplete search as the number of hits exceed 1 million. Given the limited time available for the examiner it would be a serious search burden.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The amendment filed on 11/25/2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: Applicants have substituted 7b for 1 on pages 15-20 and assert that this is not new matter. This is not persuasive. Applicants assert the position number one is not a chiral center but there is "1aS" and "1aR" in these pages besides deleted 1. Hence it appears that applicant is adding new matter by asserting a new position 7 as chiral center. Contrary to applicants'

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urging one trained in the art may not arrive at position 7 as the chiral center originally intended.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have substituted 7b for 1 in claims 59-62 and assert that this is not new matter. This is not persuasive. Applicants assert the position number one is not a chiral center. But there is "1aS" and "1aR" in these claims besides deleted 1. Hence it appears that applicant is adding new matter by asserting a new position 7 as chiral center. Contrary to applicants' urging one trained in the art may not arrive at position 7 as the chiral center originally intended.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. The formula shown on claim 1, on which all other claims dependent is inconsistent with the definition of W. See Formula on of claim 1, Note Q and W are not joined together but the definition of W recites it is a linking group. It is not clear what is indented. Note also the floating R⁷. An appropriate correction is needed.
2. Claim 58 recites "structural formula I" but there is no such formula in the claim. If this meant to be formula recited in claim 1, then it should be stated in this claim.
3. Claim 58 also recites "quinoxaline" species. There is insufficient antecedent basis for this limitation in the claim. Note claim 1 does not permit the bicyclo ring to be a quinoxaline ring.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 9-11, 12, 14, 19, 24-25, 39 4142, 44, 46, 52-53 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Wakabayashi.

Wakabayashi et al. teaches several substituted benzolactam compounds as substance P antagonists. See page 8 Scheme A-III, compound VIII. See examples 2,

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and 6-23 on pages 16-42, especially compounds 11, 25, 37, 32, 36, 40, 44, 48, 53, 58, 64, 69, 74, 78, 82, 86, 90, 94, and 98.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8-25, 30-32, 34-39, 41-52, 55-56 and 58-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard et al. WO 94/13663.

Instant claims relate to a benzofused-hetero ring with oxo, thio or imino groups linked to piperidine containing compounds. Howard et al. in formula I b teaches several benzofused hetero ring compounds with oxo, imino and thio groups, linked to various heterocyclic compounds including the piperidine ring embraced in the instant claims for the use as anti-inflammatory agents and for treating CNS disorders.

See page 2 formula 1b and note the definitions of various variable groups, which overlap with instant heteroaryl ring bearing Y, Z, Q and W. Note also the definition of R³ of formula 1b includes group of formula VII, the piperidine ring and note the definition of various variable groups of VII also overlap with those of the instant piperidine ring. Especially note the ring 1b can be but not limited to indolyl, oxindolyl, isoquinoliny besides several other hetero rings. See page 9, lines 20-25. See examples 1-25 on pages 49-63 for compounds made.

Instant claims differ from the reference in requiring quinoline-2-one, indoline-2-one or isoquinoline-1-one group for the bicyclo heteroaryl ring.

However Howard et al. teaches the equivalency of exemplified heteroaryl rings for formula 1b in examples 1-25 with that claimed in the definition of 1b. See page 9, lines 20-25. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in benzofused heteroaryl ring and the aryl ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1, 3-5, 8-16, 19-20, 24-25, 30, 39 45, 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakabayashi et al. WO 97/03066.

Teachings of Wakabayashi et al. as discussed in the above 102 rejection is incorporated herein. As noted in examples 2, 6-23, Wakabayashi et al. teaches several piperidine compounds with no substituents on the piperidine nitrogen.

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While said compounds don't anticipate the scope of instant claims in view of the proviso of claim 1, they are very closely related, having a methyl group on the piperidine ring nitrogen or adjacent carbon. However, compounds that differ only in having H vs Me are not deemed patentably distinct absent evidence of superior or unexpected properties. See for compounds that differ only as H vs Me on nitrogen, see *Ex parte Weston* 121 USPQ 428; *In re Doebl* 174 USPQ 156 and for compounds that differ only as H vs methyl on carbon, *In re Wood* 199 USPQ 137; *In re Lohr* 137 USPQ 548. Thus it would have been obvious to one skilled in the art at the time of the invention was made to make and expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Applicants should note that the claims recite at several places recite "preferably" or "optionally substituted with one to three substituents preferably zero substituents...." etc. In addition, specification recites 08 series copending application but the number recited is not correct and examiner could check that application. Also the year of WO document applied as prior art above is not 1999, but 1994.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

V. Balasubramanian
Venkataraman Balasubramanian

02/08/2003